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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,649	06/04/2002	Pierre Belhumeur	1051-1-019	6750

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,649	BELHUMEUR ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 5-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 5-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment and response filed on Aug. 31, 2007 has been received and entered into the case.

Claims 1, 2 and 4 are canceled, claims 14 and 15 are newly added, and claims 3 and 5-15 have been considered on the merits. All arguments have been fully considered.

It is noted that in the response to the notice of sequence compliance in the previous office action, applicant filed a computer readable form (CRF) for sequence listing on 8/31/2007. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) because the CRF is not saved in ASCII text. Resubmission of CRF is required.

The claim objection to claim 6 is withdrawn due to the amendment.

The claim rejection under 35 U.S.C.§112, 1st paragraph, is withdrawn due to the amendment.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 discloses species of the indicator including Sup35p, Ure2p, Het-s protein, and combination thereof. Since claim 3 (independent claim) discloses only indicators transcribed by a gene selected

from the group consisting of SUP35, URE2 and HET-s, not the combination thereof, claim 5 is not considered further limiting the previous claim.

Claim 8 discloses the phrase "the weight or the mass". It appears that "a weight or a mass" would be more appropriate.

Claim 15 discloses "Sup35" and "SUP35". It is understood that applicant intends to use "Sup35" as a protein (Sup35p) and "SUP35" for the gene. It appears that the Sup35 in a) and c) would be appropriate to be "SUP35" since it refers to the gene, whereas SUP35 in b) would be "Sup35p" since it refers to the protein encoded.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "abnormal" and "partly" in claim 6 are relative terms which renders the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "FTIR" in claim 8 is not clear what subject matter it intends to point out. This abbreviation can be interpreted as Fourier transform infrared spectroscopy or Frustrated total internal reflection.

Claim 15 disclose species of sequences of SUP35 such as "the first 759bp

region of Sup35" or "the first 639 nucleotides of Sup35". It is not clear which point of the genomic or cDNA sequence for Sup35 is counted from. It could be from the start (initiation) codon, or from the upstream region of the gene. Clarification is required.

The species (b) of claim 15 discloses the first 114 amino acids of Sup35p. In the specification, the disclosure of "the first 114 amino acids of Sup35p" appears to be based on the prior art by King et al. (PNAS, 1997; IDS reference). According to the reference, the sequence of Sup35p responsible for forming amyloid-like filaments is residues 2-114 of yeast Sup35p (see the reference). If the claimed sequence in claim 15 is based on the reference, it is not correct to claim "the first" 114 amino acid, because it does not start with the first amino acid, rather it starts with the second amino acid. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5 and 7-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for prion form of Ure2p, which is also known as [URE3], does not reasonably provide enablement for normal Ure2p. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The current invention discloses three prion protein degradation indicators including Sup35p, Ure2p and Het-s protein, which are naturally occurring in *Saccharomyces cerevisiae* or *Podospora anserina*.

Wickner (1994) teaches that the normal Ure2p has to be converted to become abnormal Ure2p of prion form (see Fig. 1). Furthermore, Taylor et al. (1999) teach Ure2p in normal form would be soluble and not form filaments or aggregates (see p.1340 and Table 1), and amyloid formation would require additional factors, such as synthetic $Ure2p^{1-65}$, which polymerizes to form filaments, to convert the normal Ure2p. Therefore, a purified naturally occurring Ure2p, without conversion to the prion form by additional factors or conditions, would not possess characteristic features of prion proteins and thus would not enable the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Safar et al. (1993) in view of Coustou et al. (PNAS, 1997), Glover et al. (Cell, 1997; IDS reference) or Wickner (Science, 1994).

Claims 3 and 5-15 are drawn to a method of evaluating the efficacy of a sterilization process using the steps of a) subjecting one or more prion protein degradation indicator a container to the sterilization process and b) determining the level of degradation of the indicator, wherein the indicator being Sup35p, Ure2p or Het-s protein; a limitation of the indicator being a purified naturally occurring form, a recombinant, a mutant, or a fragment thereof, wherein the indicator being insoluble in non-ionic detergents, resistant to proteases, forming amyloid filaments composing beta sheets; a limitation to the indicator being a biochemical indicator; the step of determining the level of degradation of the indicator being performed by immuno-enzymatic method; the sterilization process being sterilization techniques using alkyl-containing chemicals and/or oxidizing sterilizing agents or chemical exposure using a detergent; the amount of indicator being between 0.1 ng to 100 g; the container being of a glass material; a limitation to the indicator being a purified form naturally occurring in *Saccharomyces cerevisiae* or *Podospora anserina*; a limitation to the fragment comprising a) the first 759bp region of SUP35, b) the first 114 amino acids of Sup35p or c) the first 639 nucleotides of SUP35.

Safar et al. teach a detection of inactivation scrapie prion protein (PrP27-30), which is an analog as well as a fragment of a prion protein (biochemical indicator: claims 6 and 7) in a petri dish (glass: claim 12) after treatment with proteinase K (protease/enzyme; chemical exposure: claims 9 and 10, see Results) or SDS (alkyl-

group containing detergent; claims 9 and 10; see Fig.1) for inactivation (see Materials and Methods). Safar also et al. teach the detection was performed by Western blotting analysis (immuno-enzymatic method; claim 8: see Fig. 1).

Safar et al. do not teach the use of Sup35p, Ure2p or Het-s protein as an indicator.

Coustou et al. teach Het-s protein from *Podospora anserina* as an analog of a prion (see whole document).

Glover et al. teach Sup35p in *Saccharomyces cerevisiae* as a Yeast prion (see whole document). Glover et al. also teach an N-terminal fragment of Sup35p (residue 1-123) and a fragment NM comprising residues 1-253 (thus first 759bp of SUP35) of Sup35p (see Fig. 1), as well as a full-length Sup35p.

Wickner teaches the product of a chromosomal mutation in URE2 gene, called [URE3] is a prion form of Ure2p (see whole document).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use one of yeast prion analogs of Ure2p, Sup35p and Het-s protein taught by Wickner, Glover et al., and Coustou et al., respectively. This is because a person of ordinary skill in the art would recognize that the yeast prion analogs have the same property as mammalian prion proteins, and thus suitable for replace the mammalian prion proteins as an indicator.

M.P.E.P. §2144.07 states "The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945)

(Claims to a printing ink comprising a solvent having the vapor pressure characteristics of butyl carbitol so that the ink would not dry at room temperature but would dry quickly upon heating were held invalid over a reference teaching a printing ink made with a different solvent that was nonvolatile at room temperature but highly volatile when heated in view of an article which taught the desired boiling point and vapor pressure characteristics of a solvent for printing inks and a catalog teaching the boiling point and vapor pressure characteristics of butyl carbitol. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.)".

Although Safar et al. in view of Wickner, Glover et al., or Coustou et al. do not particularly teach the amount of indicator being 0.1 ng to 100 g, the reference teaches the amount of scrapie prions in molarity. Safar et al. teach that the amount of prion protein (PrP27-30) used in the method is 0.9 nmol in total 150 µl of water, and the mean molecular weight of each residue is 109.5 (see page 2214; CD spectroscopy). Moreover, it is well known in the art and an inherent property of PrP27-30 to have about 142 amino acid residues supported by Prusiner (PNAS 1998, 95:13368-13383; see Fig. 2). Thus, a person of ordinary skill in the art can calculate the amount of PrP27-30 used in the experiment, and it is about 140 µg (claim 11).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Safar et

al. (supra) in view of Wickner, Glover et al., or Coustou et al. in further view of Feldman et al. (Compatibility of medical devices and materials with low-temperature hydrogen peroxide gas plasma, 1997).

Claim 9 is directed to limitations to sterilization process of claim 3 being performed by sterilization techniques using low temperature gas plasma or oxidizing sterilizing agents.

Safar et al. in view of Wickner, Glover et al., or Coustou et al. teach the limitation of claim 3 (see above).

Safar et al. in view of Wickner, Glover et al., or Coustou et al. do not teach the use of low temperature gas plasma or oxidizing sterilizing agents for inactivation/sterilization process.

Feldman et al. teach the use of sterilization process to inactivate prion using oxidizing agents such as hydrogen peroxide as a form of low-temperature gas plasma (column 30, line 33 through column 34, line 42).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the inactivation/sterilization process in the method of Safar et al. in view of Wickner, Glover et al., or Coustou et al. with a sterilization technique of Feldman et al. using oxidizing sterilizing agents.

The skilled artisan would have been motivated to make such a modification because conventional sterilization techniques taught by Safar et al. have disadvantage such that high temperature may cause damage and safety concerns and steam also can corrode metal materials. However, the sterilization technique of Feldman et al. is

safer and has no detrimental effects on containers made of various materials.

The person of ordinary skill in the art would have had a reasonable expectation of success in replacing sterilization technique of Safar et al. with that of Feldman et al. because such sterilization techniques of Feldman et al. is commercially available at the time of the invention made. For example, Sterrad system (Advanced Sterilization Products) using a sterilization technique of Feldman et al., which is commercially available.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claims 9, 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safar et al. (supra) in view of Wickner, Glover et al., or Coustou et al. in further view of Dresdner Jr. et al. (US 5,357,636).

Claims are directed to a limitation to sterilization process being performed by sterilization techniques using ozone-based exposure; a limitation to chemical exposure using sodium hydroxide; a limitation to a container being porous, permeable or semi-permeable.

Safar et al. in view of Wickner, Glover et al., or Coustou et al. teach the limitations of claim 3 (see above).

Safar et al. in view of Wickner, Glover et al., or Coustou et al. do not teach ozone-based exposure (claim 9), or sodium hydroxide as chemical exposure (claim 10).

Dresdner Jr. et al. teach the use of ozone (column 22, lines 44-52) or sodium

hydroxide (column 27, line 48) as antiseptic composition.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use antiseptic compositions of Dresdner Jr. in the method of Safar et al. in view of Wickner, Glover et al., or Coustou et al. to test the efficacy of these sterilization techniques in elimination of prion proteins.

A person of ordinary skill in the art would recognize the use of ozone or sodium hydroxide of Dresdner Jr. et al. as an art-recognized equivalent to the sterilization technique used by Safar et al. in view of Wickner, Glover et al., or Coustou et al.

M.P.E.P. §2144.06 states "In re Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of

electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.)."

Safar et al. in view of Wickner, Glover et al., or Coustou et al. do not teach the container being porous, permeable or semi-permeable.

Dresdner Jr. et al. also teach a porous and liquid-permeable medical glove for sterilization process (column 18, line 40; column 23, line 56).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace a glass container of Safar et al. with a medical glove of Dresdner Jr. et al.

The skilled artisan would have been motivated to make such a modification because contamination of prion proteins can happen in various different materials such as plastics, metal, or polymer, sterilization process should be carried out in various materials. Moreover, medical gloves are routinely used in hospitals and laboratories and are subject to prion contamination. Therefore, medical gloves of Dresdner Jr. et al. can be used in place of a glass container of Safar et al. to determine effectiveness of various prion sterilization techniques without damaging the material containing a prion protein.

The person of ordinary skill in the art would have had a reasonable expectation of success in replacing a glass container of Safar et al. with a medical glove of Dresdner Jr. et al. because medical gloves used in hospitals and laboratories are subject to routine sterilization to decontaminate pathogens such as prion.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 9:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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